



HIT Policy Committee Safety Task Force Transcript June 23, 2014

Presentation

Operator

All lines are bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Safety Task Force. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. David Bates?

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, David. Jeannie Scott?

Jeanie Scott, MT, ASCP – Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jeanie. Jodi Daniel? Jon White?

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jon. Marisa Wilson? Mary Beth Navarro-Sirio?

Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer - McKesson Corporation

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Paul Tang? Hi, Mary Beth.

Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Paul Tang?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Peggy Binzer? Hi, Paul. Steven Stack?

Steven J. Stack, MD – Chairman – American Medical Association

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Tejal Gandhi?

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Good morning. And Toby Samo?

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And are there any ONC staff members on the line?

Amy Helwig, MD, MS – Medical Officer, Office of the Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Amy Helwig.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Amy. And with that, well turn it back to you, David.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

Great. So the plan from today – for today is to hear from Sarah Corley from EHRA and then from Greg Nelson from ASIAs. We’ll then – we’ll have the opportunity to ask each of them some questions. We’ll then basically go through and recap where we are. We have some time to discuss what our recommendations will be today, and then we have just one more call before we have to make our final recommendations to the Policy Committee, which will be July 7. So, hoping that what we have today is reasonably close to what we will recommend at the end of the next meeting. So that’s the plan and any questions about that. Great. So, what I will do then is just hand things over to Sarah Corley. And thanks Sarah and Greg, thanks to both of you for doing this on fairly short notice.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Sure so thanks for having us and I’m representing the EHRA today and I was told that what you wanted to hear about from us was what our current processes were across the vendor community for dealing with patient safety issues. Is that right, David?

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

That and then what you think will be helpful in terms of getting vendors involved with the safety center.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Great. All right. So, I’m speaking not for a specific vendor, but for what we see across our membership, so you’re going to see differences between individual vendors. But in general, what I’m going to outline is the key elements for how most of us handle escalation and management of EHR-related problems that might lead to an adverse healthcare event.

So the first is issue identification. So most vendors have an internal issue logging system, which supports the capture of potential patient safety indicators. These submissions can be made both by internal staff as well as external software using organizations. Following the indicator being set of a potential patient safety issue related to a software problem, the issue is evaluated by software and clinical expert within the company. We need to clarify the issue details, the conditions and the potential impact on the patient, the medical data or the end-user. We need to also identify potentially affected software using organizations if it is limited to a subset of the software that we provide or the customers that we serve.

The next step would be mitigation once an issue is confirmed to have a potential impact. And so there are internal and external communication plans developed to notify the affected software using organizations. That documentation is published to the potentially affected users of the product. Most vendors will have a creation and retention plan for internal issue specific patient safety reports. They’ll have a mitigation strategy for temporary issue correction, as well as long-term fixes. And they’ll assist affected software using organizations in assessing the impact, identifying affected patients and repairing any corrupt data. The resolution process involves the development and distribution of permanent code fixes to the software using organizations, communications that that final correction or mitigation is available. And positive acknowledgment from the affected users confirming receipt of final correction is sometimes hard to get.

During the patient safety process, a root cause analysis will be done to identify the issues and inform future development. So usually, the vendors will have a new development, use a risk reduction strategy such as a failure mode effect analysis to analyze the potential risk of new development and develop mitigation strategies in advance. So what I've just detailed before that is what happens if something slips through, but in general, the risk analysis process occurs on an ongoing basis for new development and enhancements. So that's the current process that most vendors are following within their quality management systems.

What we are looking for in a Patient Safety Center would be for a broader look at issues that occur across the spectrum of both vendor software types of software, but also how its deployed, how its trained to understand where the critical issues are that may lead to unsafe conditions in the use of software. Because while the strategies that I just mentioned are used for problems that occur that are related to defects in the software, I think we're all aware that sometimes it's the interaction between the end-user and the software, modifications of the software at the client site or interaction between multiple software packages that can introduce risk. And it would be very useful for the Patient Safety Center to really analyze the broader spectrum of how these products are actually used and find where there may be risk that can be mitigated.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Great. So, Sarah, it's Dave Bates, it's our belief that you – that the vendors already have a great deal of information that would be – that might be useful to the safety center. What do you think it would take to get vendors to share that information with the center?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

I think that our – as part of our code of conduct, our members signing on to that code of conduct are committed to working with a PSO and I know that a number of our member companies, my company included, have signed on with ECRI for the pilot project. I think most vendors would feel much more comfortable sharing this information with a PSO than with – directly with a Patient Safety Center because of some of these issues require that protections be maintained for our clients who might have – might be using the PSO as well when it's a multifactorial incident.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Um hmm. And I think that's the way people are imagining that this would work. There probably will be relationships with multiple PSOs, so it'll be important for the safety center to be able to aggregate information across some of the – or access information that's come in through multiple PSOs. Can you tell me which code of conduct you're referring to?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

The EHRA code of conduct for vendors.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Okay. Other questions?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

This is Paul Tang. Sarah, a couple of things, one you said vendors would be more comfortable sharing with a PSO rather than the safety center. One, I guess you – I'm assuming that you're saying the safety center wouldn't be a PSO. And two, you probably wouldn't mind if a PSO that you reported to shared aggregate information with the HIT Safety Center, is that correct?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

So, with the PSO process of sharing information, it's de-identified and we would expect that the PSO would be – that it would be fine to share that aggregate information as long as the vendor name was de-identified.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay. And then you also mentioned you – your company is working with ECRI. How did you choose ECRI as the PSO you wanted to share with?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Well ECRI approached the EHRA; they are doing a pilot now to – because we were not really finding PSOs that were interested in focusing on health IT specific issues. So ECRI came to us with this proposal, and I know that a number of our members have signed on with it. It's early in the process, but we're looking forward to learning how we can better work together, so the relationship is that we are analytical contractors to the PSO and we're working through what protections we have and don't have under the Patient Safety Act, which is a fairly complicated process. But we do have a lot of large vendors that have signed on to this pilot, so I expect that over the next year or two, we'll start to see a good bit more data being collected with a focus on health IT.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Hey, Sarah, it's Jon White. So it sounds like within the EHRA you all have done some talking about this issue. It also sounds like you're sorting through various responsibilities, have you all at this point undertaken any analysis across the group of different activities that have happened that different vendors try to pull them together yourselves to try to get a better handle on what's happening across your group?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

Well, there's – we already have some member companies that belong to PSOs or have their own PSO and have worked with PSOs, but there hasn't been a lot of data that we can use to learn from yet. So as I say, we just started this process of having larger numbers of us participating with a PSO and we do meet regularly to, our Patient Safety Workgroup, to discuss this, but to date we just haven't had a lot of information to see how it's going to work or not. The last attempt was the PDR companies PSO where they did involve vendors, but they disbanded that PSO rather quickly, so we didn't have much time to work with them then. What we found then was they did not have adequate resources to really do root cause analysis into issues and so we are hoping that this pilot will be able to see that there will be adequate resources dedicated to really understand the root cause of these issues.

And where they can be generalize, because of course vendors have very different products and data structures, and so it's going to be complicated to understand what you can generalize and what you can't. More training equates to less patient safety issue, okay, that's easy to say you could generalize that across all vendors. But when you're talking about use of radio buttons and how you code that in the background, I think there's going to be a lot of variability in how the code is written. So, we may not be able to have enough data on that to generalize on how best to write code.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Okay, that's helpful. At the point at which you all get engaged with ECRI, it sounds like the various vendors have their own information that they've been gathering over time in their internal tracking systems. You mentioned root cause analysis, so it sounds like there have been some resources applied to doing that sort of on a vendor-by-vendor basis. Do you all plan, if there are protections present, to be able to share that past history on a vendor-by-vendor basis with ECRI to see if there is some more sweeping analysis that can be undertaken?

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems

I can't speak for other vendors, we personally do plan on sharing that retrospective information to hope that we can have further insight and –

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Cheers to NextGen.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Great. Other questions for Sarah? Okay, well thanks so much, Sarah. Next, we'll hear from Greg.

Greg Nelson, MPP – Principal – MITRE

Good morning and thank you Dr. Bates and other members of the HIT Policy Committee Safety Task Force, my understanding this morning is you wanted to hear a little more about the ASIAs Program. And as well as we have some thoughts on how it might be a model for the HIT Health IT Safety Center, or at least some lessons learned that might apply. So we can go to the next slide. I thought I'd begin just to give a little background on MITRE, for those of you who might not be familiar with us.

We're a non-profit organization working in the public interest. We've been around over 50 years and we are in the business of operating what are called federally funded research and development centers, which is a mouthful of an acronym commonly referred to as FFRDCs. We currently operate on behalf of six government agencies, they're FFRDCs. We started in the defense world during the Cold War and have progressed to other parts of the federal government, focusing primarily on systems engineering and technical services. And our most – we were recently awarded, 18 months ago, the newest FFRDC, which is for the Department of Health and Human Services. And one of the keys to the FFRDC concept is that there are no conflicts of interest, we can only work on behalf of the federal government and that tends to create a safe harbor that industry and the government will work with us and share information that tends to be very beneficial for our sponsors.

Next slide, please. So I thought I'd – a little context for how the ASIAs Program came to be. This is showing the – for the last 30 years, the red line is the fatal accident rate in the US and the green line is showing the level of departures in millions. And if you kind of look at the first 15 years on that slide, there was a lot of concern that with the increase in departures, the fatal accident rate was not decreasing fast enough. And there were a number of activities started in the mid-90s, including a commission by Vice President Gore to try to really focus on new approaches to aviation safety. And those had a beneficial effect, as you can see, and the fatal accident rate has decreased.

But that presented a new challenge, because the traditional way of improving safety had to do with looking at crashes, right, and the NTSB type investigation of root cause analysis, which is still very important. But if you're living in a world where there aren't very many crashes, and there have only been two in the US with US based aircraft in the last 7 years, you needed a new model, something to – a new approach to safety. And that's where the ASIAs Program got started about 7 years ago. And the next slide, please.

So the traditional focus has been on, as I said, kind of what went wrong, what's this, and that's still very important and that work continues with the NTSB and others. But the ASIAs Program and next click please, is really focused on what could go wrong and using data to try to look forward and identify issues before they turn into fatal accidents. And it complements the traditional approach, it does not replace it, they work very in synergy together, but that's really the focus of ASIAs. Next slide, please.

So ASIAs is a collaborative government industry initiative, so it is a voluntary partnership, if you will, between the federal government and the aviation industry, focusing on data sharing and analysis and trying to proactively discover accidents or incidents before they occur. And then also facilitating a discussion around mitigation of those risks and then measuring the effectiveness of those mitigations and those prevention standards to ensure that the changes that are made to the system actually are improving safety and really closing the loop all the way back to the beginning, to try to provide a safer system. Next slide, please.

ASIAs currently started with five members seven years ago; it has expanded over these last seven years. There are currently 45 air carriers who are members of ASIAs that represents roughly 98% of all US commercial flight operations in the United States. There are also representatives from the US government; obviously, the Federal Aviation Administration is the significant representative there. They are there both as their mission of promoting aviation safety as well as they're a participant, because they operate the air traffic control system and generate lots of data that is used in the ASIAs program. There are also industry represented, aviation is a heavily unionized industry, so most of the major airline unions are there, as well as the aircraft manufacturers as well as trade organizations. One of the themes of ASIAs is that everybody has to have a seat at the table if you're going to come up with effective both analysis as well as mitigations, everyone needs to be participating. Next slide, please.

Data – diverse data is collected to do ASIAs studies. First click shows that the – we started with user reports – voluntary user reports that are collected by the airlines, the controllers, the mechanics and aggregated those across the partners. And although that was important, we realized that really wasn't going to be a game changer in terms of really gaining insights. And the next click, please. So it was only through adding data from the digital flight data that – you can think of that as the equivalent of the black box data, pulling that information from flights to really understand the scope of problems. Next click, please.

In addition, we've pulled in information from the air traffic control system and principally the 220 radars that are across the United States measuring every – tracking every aircraft in the sky. Next click, please. Combining that with safety data that is reported to other agencies, NASA has a safety reporting system, we – ASIAs works with the NTSB on safety data. And finally, next click, when you're dealing with aviation safety, weather and wind are important factors in many incidents and pulling those kind of information together. So I would say one of the keys to ASIAs' success and that growth from 5-7 airlines has been the ability to collect this diverse data and leverage what's already being collected, right? All of this data was already being collected by the airlines, but ASIAs was the first to pull it all together and try to do that fusion and that analysis. And that's really one of the reasons it's had the success it's had.

Next slide, please. The ASIAs Program has a strict governance process. As I said, it's a voluntary partnership; it's co-led by industry and government. It is not a giant collection of data that anyone can swim around in and do analysis, it is the data, what is collected and how the studies are conducted are managed by an executive board and a number of other panels. And they are focused on studies, they can take a variety of different flavors, directed studies involve looking at a particular issue that has been identified across the community and wanting to look at it. Safety risk assessments are looking at once a risk has been identified and a mitigation implemented, we want to measure whether the mitigations are having the desired effect and so those are measured over time.

Benchmarking operations are one of the most successful of the studies that are done and probably the most valuable for the individual airline participants. For the first time they are able to see how their airline ranks against the industry average on a set of currently 24 predictive metrics. And finally, vulnerability discovery is looking at subsets of data and trying to find the outliers in kind of the classic trying to find we don't know what we don't know. And so there is some basis of trying to look at the previously unknown vulnerabilities in the system. Next slide, please.

All of this data analysis wouldn't be any value if it could not be shared with the partners in a useful format that they can leverage in their daily operations. And so if you click on the next slide, please, you can click two more times, there are a variety of different dashboards, depending on the type of member you are, that you would see. It's a secure dashboard, you are only going to see the information for your particular organization or airline relative to industry averages. There are strict firewalls in between; no one is seeing anyone else's data. That middle chart there is showing some of the metrics that have been developed, and if you were to click through on that.

You would get a more detailed slide as shown in the lower right that you are able to customize and look at individual airports and study if you have an incident. For instance at your airline, and were interested in understanding the number of unstable approaches or missed approaches that you had relative to the industry average, you could look at this dashboard and bring that – those kind of metrics out. I should mention at this point that doing metrics, as I'm sure all of you know, is very challenging.

And when we started on this process, we had five airlines and we had about eight different definitions of some of these metrics, and so there's been a lot of work on coming up with some common definitions. And it's not that each airline then has to adopt that internally, they can keep measuring however they have traditionally been measuring, but there obviously needs to be a common metric so we can do these comparisons. And a lot of work has been done through that facilitation, to make sure that the metrics that we are developing are useful for the partners. Next slide, please.

MITRE acts as the trusted third party of the ASIAs program; we serve a number of important roles. We host all the data in a secure database and we integrate that data together. We are developing analytical capabilities and fusing those diverse data sets, which is where all the power is, but many of the data sets both within a particular airline, but as well as across airlines, were never meant to be fused together. And so a lot of work in trying to figure out how to do that effectively. We are then able to do predictive safety analysis and develop new algorithms on things we identify, and then we frequently share those techniques and tools with the partners so they can apply it on their own data, as they would like. And then we provide access to those results and tools through the data portal, which I just showed you. And finally we're facilitating that collaboration among the public and private partners. And this again is why the FFRDC role is so helpful for us in that we are a – we can do that without being perceived as having a conflict of interest. Because the private partners know we are not going to compete with them and we're not going to share their data with anyone else. And the government can trust us because they know we are not going to be used as an industry contractor. So the next slide.

The kind of in a summary, the ASIAs is really a national aggregation of individual data, so it's taking what's happening at any individual airline and trying to find national trends. The integration across multiple data sets is really what sets – provides the value for this. So multiple data sets means both within an airline, both looking at voluntary safety reports but as well as other electronic data that's already being collected through many of the digital systems. And then using that to find those early warning indicators and predictive tools that allow mitigations to be implemented before incidents occur. And that benefits all sectors of the community from the largest airlines down to the relatively small regional airlines who would never before have the resources or the technical capabilities to do that analysis and see where they rank relative to the industry. And have those conversations with their peers about mitigations and what's the most effective way to address those challenges. Next slide, please.

So as we thought about the ASIAs Program and then looking at reports from the Institute of Medicine and the HIT Safety Committee, we've been thinking about for a number of years, how this would apply to the patient safety world. And in the last year we've launched a program to actually implement these in the healthcare world and I think there are a number of characteristics that are very similar – if you could click ahead please. Being data driven, right, everything in ASIAs is, we let the numbers speak and people can see what's with actual hard data and I think that's a value that we would see in the healthcare space as well, in terms of helping derive evidence-based solutions. Next please.

It is linking diverse data sets, there are lots of data being generated in the healthcare world, and more data every day as new digital systems come online. Let's figure out how to use that existing data in ways to work with and compliment the traditional voluntary reporting systems. Next one, please. Multiple institutions of value is seeing things across multiple institutions and letting them see – share lessons learned and have it in a – in the ASIAs Program it is a voluntary program, right, it's not a regulatory aspect to it and that gets to the value proposition that the partners see in it, that's what's generating that growth, right. And I think we are – we believe that there's – that same value proposition can be found in the healthcare space. Next, please.

Again it is focused on identifying precursors and not so much on looking at root cause analysis of individual events. That type of analysis is important and clearly needs to continue, but I think there's also value in stepping back and looking at the national – at a national scale of looking at those precursor type focus. Next, please. It is non-punitive, clearly an important factor in both the aviation and the healthcare domain that this data is not used from a regulatory point of view that will – I know no faster way that would shut down a voluntary partnership like this is if it's used in a regulatory manner. That would destroy the trust that is at the core of this type of operation. Next, please.

The – you need an entity that all of the parties trust with their data, both from an information security point of view, as well as the technical expertise to link these diverse data sets and develop those analyses. Because in many cases, as I said, these data were not necessarily designed to be linked, so how do you do that effectively is not an insignificant challenge. And the last click there is just to say that we have started this partnership validating this concept in the healthcare domain. We've been working on it for just over a year now. We've had our initial results with our initial partners and it's been very – it's validated the premise and we're very excited about it moving forward and we think there are some important lessons there that could apply to the Health IT Safety Center as well. Thanks for the time.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Great. Well thank you. Let me just ask – its David Bates; let me ask you a question or two. What do the members contribute? Is there a fee? Is that based on their size?

Greg Nelson, MPP – Principal – MITRE

They do not; the operation of ASIAs is funded by the Federal Aviation Administration as part of their mission to improve safety. But partners are – to become a partner you have to be willing to share data, right, so there is the free-rider problem of people want the benefits and so they have to agree to contribute data. The type of data and volume of data kind of varies, depending on the size of the operator. And the other component is they're providing expertise, right, in looking at that data and understanding it, they provide subject matter expertise for each of these directed studies. They participate in those workgroups and help drive the analysis.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

I wondered if you could tell us what the FFRDC that you're putting together for Health and Human Services will do first.

Greg Nelson, MPP – Principal – MITRE

Sure. Well it was awarded to MITRE a year and a half ago. So they went out to Congress, the way these operate is a federal agency requests that they need the special services and capabilities of an FFRDC. Health and Human Services and with the lead agency of CMS went to Congress and made that request and they authorized them to pursue it. And so in the only form of competition that we do, we competed for the right to operate the FFRDC and it was awarded to MITRE in October of 2012 or 2011 I guess. And the – and so we're providing a variety of services for them from a systems engineering perspective and – including one of which is related to we've done a number of studies with ONC and helped them looking at the functions and capabilities of the safety center.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Okay. And, let's see, you mentioned that the flight data were de-identified, has that been an issue? How do you figure out what happened in an individual instance?

Greg Nelson, MPP – Principal – MITRE

So all of that is – so yes, it is de-identified and that just reflects the governance, the willingness – what the airlines are willing to share and doesn't have anything to do with any technical issues, it's that they're willing to share, but not that much. So, the line that was drawn was to de-identify, so we do not know the flight number for the digital flight data, we don't know the flight number or the day, we know the month. So for the purposes, clearly there would be more that we could do and link to individual incidents, yes, but for what we're primarily focusing on, which are the significant trends and outliers. Again, we are not doing root cause analysis of any individual incident, we are trying to look at broader issues and the precursors, and that's what all of those metrics are looking at are precursors to incidents. And so we're trying to find where those unsafe conditions exist that routinely occur, but due to the scale and ability of the pilots and others in the system, they're able to recover and – but in fact, some cases they never would get reported through the voluntary system. That's where the digital flight data has been so effective is we're able to see those conditions and measure them over time and so the de-identification is – it's a limitation we're able to work around.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

You mentioned four types of analyses, are there some that have been particularly productive?

Greg Nelson, MPP – Principal – MITRE

Umm, so I would – yes, and I think part of that kind of depends on your perspective, from the partnership. I think the directed studies, which have been looking at a particular issue, unstable approaches, for instance, is a type of precursor. Understanding what leads to those and what – whether it's aircraft configurations or wind or what the weather was like, and being able to address those in advance, I think the FAA would say those have been really big winners for them, because they're able to facilitate the discussions and introduce, either through themselves or through the airlines, some mitigations.

If you were to look at individual airlines, they would say that's important, I think they would rank this benchmarking capability and the fact that for the first time they're able to see how their airline on a particular metric at a particular airline measures against the industry average. And even more important, they're able to see if changes that are introduced to try to reduce that risk actually have the desired effect. And so I think they would rank the benchmarking type studies as the most valuable.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Great. Questions from others.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

David, it's Paul Tang, I have three questions. One, what is the budget for ASIAs?

Greg Nelson, MPP – Principal – MITRE

I would have to – I'll have to do some research and get you the most current number. I wouldn't want to err, but I can do that, it's a publically available number. We can track that down.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I mean is it 10, 100 mill – I mean, just around –

Greg Nelson, MPP – Principal – MITRE

No, it's in the – it's a round figure it's in the – it's somewhere between 10 and 20 million dollars.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay, that's helpful. And so in your work with ONC – you said you're working with ONC on I don't know whether it's spec'ing out some of the HIT Safety Center functions or something, but do you have a sense – is that the same ballpark it would cost for an HIT Safety Center if it's modeled like the ASIAs?

Greg Nelson, MPP – Principal – MITRE

So that's a hard question to answer, because clearly the – I guess the answer there is, it's all a matter of scale, right. So one of the keys to ASIAs was starting relatively small, with a core group and kind of getting some of the bugs worked out and building that trust and validating the concept and then expanding it as it worked. As I said, it's been going for 7 years. And it I think in general our experience with these partnerships is because they are based on trust and getting value that you need to start relatively small, with a core group and with long-term success in the plan, and then being able to understand what this partnership would look like at scale. So that's a difficult question to answer in terms of what that would ultimately look like. It would be around what the focus and how many studies and how many airlines and how much data and there are technical answers to that, but there are also other factors that are going to influence the volume of data you get.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Sure. And you talked about the digital data you get from like ATC, are you getting all the data or only data that you request or, how does that work?

Greg Nelson, MPP – Principal – MITRE

So we are getting all of the data from the radar systems, but that's because the FAA owns all of that data and they share it with us. From the digital flight deck data, we are only getting data that is supporting specific studies, right. So the airlines are not just sending us direct data from – they are sending us data if we're studying unstable approaches for a particular set of airports, they would send us the data that relates to that – those airports in that length of time period. And then there are also strict, as part of the governance, there are strict limits on how long we can have that data, most of it is three years, and that's again due to what's in the governing document and our partnership with the airlines and their willingness to share.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thank you. And final question is, so you're talking about how you focus on the precursors and don't do investigations of accidents. So that's to compliment what NTSB does and the voluntary sort of near miss reporting that the pilots do, that's all completely separate. And I guess you're saying that your precursor work does – I mean the NTSB and the Aviation Safety System doesn't do that? I'm trying to see how mutually exclusive your activity is with what goes on linked to the NTSB and the NASA system.

Greg Nelson, MPP – Principal – MITRE

Oh sure, yeah. So they – if you think of it from a data point of view, it's in fact using all the same data, right, when the NTSB does an investigation they're looking at safety reports, they're looking at the black box data and in some ways, so is ASIAS. But it's what we're doing with the data and the triggering event, right. The NTSB, the trigger event for an NTSB investigation is there has been an accident and then they go into action and say, we need to figure out the cause of that particular accident. The triggering event for ASIAS is the executive board composed of the airlines and the government has said, hey, we think there is a risk in unstable approaches. We want to study how are – is the trend line in unstable approaches going up or down over the last five years at which airports and what are the characteristics. Is it speed? Is it weather? Is it type of aircraft? And so to do those studies, we are using the same data, if you think about it, that the NTSB would do for an individual, but they are looking at a specific incident and we are looking at things in the aggregate. Does that help?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

It does, but I thought pilots also have a voluntarily report sort of near misses or incidents –

Greg Nelson, MPP – Principal – MITRE

Yup, yes and the –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

– and wouldn't they be in – looking at that prospectively, looking for potential risks as well?

Greg Nelson, MPP – Principal – MITRE

Yes and that is one of the data sources that we use in ASIAS. That's actually one of the initial ones we used is we have all of that voluntary reporting that is either pilots can either report to NASA has a program, every airline has an internal program that pilots – commercial pilots report to, and we have access to all of those reports. The airlines share those with the ASIAS Program.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thank you very much.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Yeah, this is Toby Samo. So this is fascinating and I think sounds like a very high potential model that we could use to facilitate the implementation of the national patient safety database, the little that I've heard. But one question about how – are there guidelines as to how that data can be used by the airlines? So for instance, I can't remember ever seeing an airline coming out in their advertising saying, here's where we are in the safety quartiles. So, are there, shall we say, guidelines as to how that data can be used?

Greg Nelson, MPP – Principal – MITRE

Yes. And all of that has been negotiated among the partners themselves in the governing document for ASIAs. So part of when you sign up, I mean the initial partners negotiated it among themselves and if you're a new airline and you wanted to join, you would have to sign in as part of the governing and part of that is the restrictions around what can be done with the data.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Thank you.

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

Hi, this is Tejal Gandhi. I had a question for you as well. I think the analytics piece, in terms of bringing in disparate data sources is really interesting. How do you – two questions actually, so can you talk a little more about actually creating what the best practice or solution might be once you have sort of aggregated this data and potentially found a risk area? And then second, you mentioned that you're not regulatory, and then can you talk a little more about actually dissemination of what you're learning and ensuring that those actions actually get implemented?

Greg Nelson, MPP – Principal – MITRE

Sure. So on the first one about how does the examples of learnings, I guess, right. So for a particular study, for example we're – we would, and I'm going to make something up, right. So we see that there is an increase in these unstable approaches at a particular airport. Typically there are multiple ways, once we understand those characteristics, then the partners get together, and there are multiple ways to introduce mitigations, right. It is not obvious the one way to solve this problem. You could have the controllers change their training, so that they guide pilots into the airport using a new procedure, so that involves the FAA doing retraining and writing new procedures. You could say, well or we could address it through a software fix in the – on the aircraft, and that involves those vendors. Or you could say, we should be looking at the pilots, and retrain the pilots to adopt this new procedure.

And so part of this discussion that goes on through ASIAs and some other committees related is, coming to an answer about what makes the most sense in any one instance. The underlying motivation for people to participate, in addition to wanting a safer system, is that they know that if they can come together and implement a mitigation. What no one wants, including the FAA, is to have to go through the regulatory process, because that is longer and it just isn't in anyone's interest. So that's part of what motivates people to participate in these types of discussions and coming to a resolution. Could you remind me your second question again?

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

Well it ties into, I think, what you just said, which was, given that you're non-regulatory or not regulatory, how do you ensure that actually the recommendations you have get implemented? But I think you –

Greg Nelson, MPP – Principal – MITRE

Right.

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

– touched on that.

Greg Nelson, MPP – Principal – MITRE

Yup, and yeah, so that's the short answer.

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

Thanks very much.

Greg Nelson, MPP – Principal – MITRE

Yup.

Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation

This is Mary Beth. I had a question. You mentioned your executive board, can you just tell us a little bit about how that group functions and how much time they spend devoted to the ASIAs activities and just general description of that?

Greg Nelson, MPP – Principal – MITRE

Sure. It is Co-Chaired by a representative from the FAA and a representative from industry. Initially there were some airline – direct airline members on there, as we have grown, the – one of the airline trade groups kind of takes on that Chair position and represents all of their members, but that's – they agreed to do that, just because they thought that made the most sense. They meet formally quarterly, I believe. It is – and again, the executive board is providing the strategic direction, so they are saying, these are the kind of studies that we should be doing and these are the – and the results are reported out to them and kind of where – what – where it makes sense, appropriate to forward those studies to other stakeholders, all of those decisions. So basically they're making the decisions about what study is to be done and where the information, once the studies have been finished, where that information needs to most appropriately be shared.

And then there are working groups and other, that happen underneath that actually that involve more broader number of participants and more time, because that's where the actual analysis is being conducted and mitigations identified and so forth. And those – twice a year we have large, everyone gets together kind of live or virtually to work through those and share some of those studies. And people in the aviation community find those at the – kind of the safety – if you're the Director of Safety, kind of level in an airline, those are the most meaningful. Because you actually get to interact with your colleagues for a few days on these topics, and have real data to talk about as opposed to previously, one of the frustrations with many folks in this – with it, was a lot of conjecture and anecdotal information. And here, although there's still much work to be done, at least the starting point of the discussion is based on data, and that's been pretty helpful.

Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation

Yeah, great. Thank you. It sounds like it's somewhat analogous to where we are as far as a lot of anecdotal data, but not a lot of analysis to support some of the issues that we might face.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

I'm sorry, you said it was Co-Chaired by a member of industry and –

Greg Nelson, MPP – Principal – MITRE

The Federal Aviation Administration.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thanks.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

Okay, other questions?

Steven J. Stack, MD – Chairman – American Medical Association

This is Steve Stack. I don’t know – I’m struggling how to frame this but, clearly there’s a myriad of different things that you could explore and you had to, in the creation of this enterprise, come up with a smaller start that I guess you would have expanded over time. Are there any insights you can offer me? As we would look to create a safety center for Health IT, the landscape for potential issues is so enormous and there is so much complexity as to lessons maybe learned when the aviation industry created its – this activity that we might benefit from as we try to do something similar for health IT?

Greg Nelson, MPP – Principal – MITRE

Sure. So as I said, I think it’s – we started with a select – a small group of airlines and it was people who were – who really believed in this, right? Because when they first, I still remember the story, when they first got together, I was not there in room, but the guy from Continental tells a story, he looked around at his peers and these guys from the FAA and MITRE and was – they all kind of were looking at each other. There was a lot of doubt whether this would really work, right, there was no guarantee and so there was a lot of trust right, that they had to believe that they were going to stick through this for the initial month and years to believe in this. The other aspect is starting small with folks who are willing to persevere through it.

The other is to identify those initial studies that they are big enough to be meaningful, but not so huge that it’s going to take years to generate results, right. So you don’t probably want to start with the – necessarily with the toughest challenge out there, you want to start with something that you can – the data is relatively clearly identified in terms of what it will take to look at. And that you’re hopeful that you can turn results around in a matter of months and prove the value. And that’s kind of where we saw, in the aviation world, is kind of this classic hockey stick kind of approach, if you were to look at the ramp up in terms of membership, is it took a couple of years to kind of get the thing going. But once the value was discussed, it quickly – word quickly got out to the other airlines that you should be part of this, this is really giving us new insights we hadn’t seen before and we saw that increase. So I think that would be a similar type of model that probably makes sense in this world as well.

Steven J. Stack, MD – Chairman – American Medical Association

Thank you, that helps a lot. Thank you very much.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

Great. Any other questions for Greg? Okay Greg, well thank you so much, this was extremely valuable.

Greg Nelson, MPP – Principal – MITRE

My pleasure, thank you for the invitation.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

Great. So could we go to the next slide set? Great. So again, our charge was to respond to the FDASIA Health IT Report, to provide recommendations about the safety center. We’ve talked about the governance structure needs to serve as a central point for a learning environment. It should complement other systems, facilitate reporting, promote transparent sharing of things like adverse events and near misses, the lessons learned and best practices. Next slide.

And we were asked to consider the three “Es” which are engagement, bringing stakeholders to the table, we just heard a lot about that, evidence, serving as a mechanism for education for broad groups of stakeholders to enable rapid learning and better safety and broader improvement. And finally education, moving data to information to knowledge that fosters improvement. Next slide.

On June 13, we heard from a variety of others. We heard from David Mayer from NTSB who told us about what NTSB does, they focus very much on investigation. The issue is that ONC, however, does not have investigative authority. We’ll come back to that. We then heard from Bill Munier at AHRQ who administers the PSO program and the Common Formats for safety reporting. The feeling was that the safety center could leverage this and partner with AHRQ and others. We then heard from Jeanie Scott at VHA. She told us about the Health IT Safety Center and how it does its analysis and prevention and focus on HIT related events in the VA system. And I think the variety of lessons that the safety center can draw from that. And then Ronni Solomon from ECRI talked about the partnership for HIT Patient Safety, which is effectively an approach to bringing together data from a number of PSOs. And Ronni went through some of the – how to actually make that happen and some of the early lessons learned. Next slide.

So again, we were asked to focus really on four main issues, the value proposition, the governance, the focus and the function. Next slide. And with respect to value, what we’ve discussed is that the Center will be a place to analyze data from different sources, to disseminate best practices. That it will need to provide value and improve safety at a national scale. That it will offer some specific defined products and that it will provide services that make stakeholders in the healthcare system feel a vested interest in HIT Safety. I think we just heard about how that has worked in the airline industry. Next slide.

From a governance perspective, the notion is that this would be a public/private partnership, would sit outside of ONC, but it would be resourced at least in part by ONC, although some private funding would also be desirable. It is felt that it’s important that the safety center have a clearly defined mission, related priorities. That it should avoid duplication of existing activities and complement the other things that are already going on. We’ve looked to other industries, in particular the airlines industry, for examples of success. We’ve also heard from some groups that are doing very closely related things within healthcare. Today we heard from ASIAs, before we heard from NTSB. I think it’s clear that the safety center would need an advisory group from outside, which would include industry members and I think there are some analogies to what we just heard – between what we just heard and what the safety center’s advisory group might look like.

Next slide. There are some issues within governance, consumers both healthcare providers and patients expect the systems that they use to be safe and many of the existing HIT and safety partnership activities provide valuable lessons, with one example being the Partnership for Promoting Health IT Patient Safety, which facilitates providers, PSOs, medical societies and vendors in addressing safety issues. But there are some significant challenges. We have to have incentives for reporting events. We have to be able to identify the HIT related events, and it’s often hard for frontline reporters to sort out which ones are really HIT related. Next slide.

With respect to focus, the points that emerged were that we should cover all types of HIT, not just electronic health records that the focus should be on learning and not enforcement. That it should consider sociotechnical issues as well as just the technical, we've heard repeatedly that that's really important. It should incorporate a variety of data streams and not just adverse event reports including things like near misses and hazard reports. And again from ASIAs, we just heard about some approaches that they've used to bring together a variety of data streams. That it should rely on evidence when it's possible to do so, that it has to include multiple disciplines and it should cover both broad trends and individual events. Next slide.

So another way of thinking about this is some of the key functions are engagement, and that would include of the key stakeholders notably the vendors, the providers and others, the federal government. Analysis will be a key role in terms of aggregating data streams of multiple types, which would include data from, but not limited to, the data from PSOs. It would include a major convening function, which would enable identification of best practices. The education and dissemination would also be important that would be both for vendors, but – for providers, but also for frontline reporters. And the concept is that you'd help the frontline reporters decide what to report and to use definitions and tools for standardization of reporting. Next slide.

It's come up repeatedly that there are still issues with usability. One proposal that came forward is this might become part of certification; user-centered design is already a part of this. And there was, I think, consensus that there should be two-way learning between the safety center and the certification program. The role of the safety center and post-implementation testing, if any, would have to be defined. It clearly would promote the SAFER guidelines, which have been – which I think are really a nice set of guidelines that AHRQ sponsored. Next slide.

Other things that came up, ONC does not have the statutory authority to investigate and one thought is that it might be better for the safety center itself not to perform investigations, even though it will be outside ONC. Lots of other safety centers do do many investigations, but the safety center could partner – for e – with others like PSOs, that do investigations and this could be handled that way. The safety center will not be regulatory, it won't make policy, it won't develop standards itself, although it might identify areas in which standards were needed. Another thing that came up, which we might want to talk about a bit is, been told by one of the lawyers at the Office of the National Coordinator is that the safety center itself would likely not have the protection that PSOs do. I guess that does not necessarily mean that it couldn't over time potentially form a PSO, but it would largely, I think, be working with the PSOs and it would be collecting data from the PSOs, so that would be a way around this. Next slide.

Several things came up that we should avoid. Those include interrupting the relationship between clients and vendors in which safety information is already coming in that's working well, duplication with existing efforts and then, as noted earlier, assuming that reporters can necessarily define whether or not an incident is HIT-related. Next slide.

So na – I think we have consensus again that the safety center has the potential to deliver substantial value. It will need adequate resources; we still don't know exactly what those resources are, although it's helpful to have some benchmarks from other industries, as we heard today. It's also clear that it will have to engage the key stakeholders effectively. And this again is the list of some of the key functions. Next slide.

So, I'm going to open things up now. We will have our final discussion on July 7; we'll be presenting to the Policy Committee on July 8, so, not a lot of wiggle room between our final discussion and the presentation to the Policy Committee. But let me just open things up to thoughts at this point and if people don't ask questions, I'll ask a couple of very specific ones.

Steven J. Stack, MD – Chairman – American Medical Association

So this is Steve Stack, if can jump in. So the question I asked the gentleman from the aviation industry I think kind of tees up one of the things I have a concern as we do this. If we try to eat the whole apple in one bite, I think we run the risk of this just becoming another frustrating and annoying activity that perplexes and bothers people and makes busy work and doesn't get where we need it to be. And so some of the key things he suggested were starting small, having a small group of people who begin with problems that are tackleable in a reasonable timeframe, not trying to save the world all at the outset.

So I would say, and I realize that not everyone may agree with this next statement but, one of the challenges we now have with the Meaningful Use Program is, since it was a big bang thing, with a big pot of money and a very short timeframe and things had to be done quickly. We tried, I would assert, to do too much too quickly and now we're kind of suffering under the burden of that. So with this, if I were to look at how I would create something like this, just off the top of my head, I'd probably want to look for a small group of three or four vendors who are willing to be committed to doing this. And a handful of health systems and provider groups that included like physicians and nurses, who are actually using these tools and get a small group of people and entities that have the resources and the staying power to commit someone to it.

So those are corporations, health systems, American Nursing Association, American Medical Association, things like that for a core group to start to identify issues. Because even though I think we need the perspective say of practicing clinicians using this, I think at the outset we're going to need people who know the technology better from vendors and maybe CMIOs, who can say here are some things that we think are trends or real challenges, but then also that can be addressed and maybe generalizable. And so you're going to need subject expert guidance at the front end for how to scope and design some of the projects. And I don't know that a frontline clinician will be the right person for that, but their input will be invaluable as we go forward.

So, I would start that way and create what would be a governance structure a cooperative way between the public and the private sounds like a nice way. And I would have some real clear things that hopefully we could agree to as a committee recommending to the Policy Committee such as, this is a non-punitive approach, it's not a regulatory approach, it is a – there – it doesn't do investigations. Because I think people trumpet what the aviation industry has been able to do and how successful they've been, but there are some key things that are different to the way they've done it that have probably helped make that success possible. And I think that if we're going to really learn from their example, we need to find those core things that really helped them to be that successful. And I think that the guy who spoke today was very, very helpful in shedding insight into what some of those key characteristics might be.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

This is Paul Tang; I'd like to chime in after Steve. One, I agree with a lot of what you presented on the slides, David, I thought it was – there were a lot of – it accurately summarized I think where we are at this point. I also was pretty impressed with the size – the whole model. I know the IOM committee recommended the NTSB, but as your slide pointed out, ONC at least doesn't have the investigatory authority. But the way that ASIAs put itself together and took its time and actually the budget's not – I was sort of surprised that it's reachable, I think.

And I really agree with what Steve just said, the takeaway about starting small, getting of folks that are determined – very interested, very determined to tackle the problem and work together to do it, I think that’s really critical and it looks like that’s how they started out ASIAs. And as Steve mentioned, if we get multiple stakeholders but all with a real vested interest in addressing this problem rather than impeding it, then I think we’ll probably get to a place where we have a good model, pick a doable initial study and start getting buy in more broadly, very much like Greg described. So, I like what Steve said.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

So both those comments resonated for me. I mean I feel like ASIAs is probably a better model than NTSB for us and that there were a lot of things to draw from what they said. I might actually include a couple of slide summary of ASIAs in what we present to the Policy Committee if people are comfortable with that.

Jeanie Scott, MT, ASCP - Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics – U.S. Department of Veterans Affairs

Hi, this is Jeanie Scott and I think just in the name of ASIAs, it resonates back to the three “Es.” It is the engagement of what they talked about, it’s that partnership trust. It was the evidence, so we have that analysis of the data. And then it’s the sharing, it’s that education part. So I think their model actually resonates back to the three “Es” is what I got out of that presentation. And again, when I’ve looked at their model – what the other two gentleman, Paul and Steve had said is that starting small, it’s going to give us that value and that trust that we need to move forward with and then to begin from there. Because we want it to succeed, so to pick that one item to move forward with, get that engagement, get the trust, get that value proposition from that one item and then move forward from there.

M

(Indiscernible)

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

This is Paul again; I – just a question, and I don’t know whether anybody on the call can answer it. He did – Greg did mention that ONC has already commissioned a study or something from MITRE, and I wonder if there can be some further detail on that, because maybe we’re on the road to something. I don’t know.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

Amy, could you comment?

Amy Helwig, MD, MS – Medical Officer, Office of the Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Sure. So we are working with MITRE, we have asked them to complete a feasibility analysis and that is in the final weeks of wrapping up, but essentially just looking for some insights on how it might – we might set up governance. How the initial safety center folks would convene, what might be some of the early best value targets and just some rough ideas on budget.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

This is Toby. So, I agree that, excuse me, that an ASIAs-like model, excuse me, is key for us to be able to make decisions based on data goes to the core of the scientific basis of medicine, and so we need to strongly encourage that sort of data collection and analysis. But I wanted to change the subject a little bit to back to governance, if that’s all right.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

Sure.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

On slide 10, you’ve got the last bullet point where it says that you would need an advisory group from outside, which would include industry members. But we don’t talk about, unless this is what you’re driving at, what the actual governance structure of the safety center would be, because the ASIAs-like model will be part of what the safety center does, but not all of what the safety center does. And so is it in our purview to at least outline what some of the actual governance structure should be?

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

I think we could certainly make recommendations about that. We haven’t talked about it a great deal, do you have specific thoughts?

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

So no, that’s why I brought that out. In that there is clearly a conflict between it being all-inclusive versus having so many people on the governance structure that nothing gets done. So, I imagine that there will have to be some core, let’s call it a board for whatever you want just for the sake of discussions. And then there will probably have to be, and I think this is what you were driving at, some advisory board that goes – that has a larger membership outside of the actual governance structure.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

Right. I mean what I was thinking is that there would be – there might be a large board which would be very inclusive, but too big to be functional.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Right.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

And then some sort of executive committee. But I hadn’t written that down, because we haven’t talked about it.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Yeah, I mean ultimately how it’s governed is going to be really key because there will be many decisions about direction to go and as a lot of the discussion today, where do we start versus where do we hope to be in 5 years or 7 years. Those are all directional issues that will be decided by this governance committee.

Steven J. Stack, MD – Chairman – American Medical Association

So this is Steve Stack again. And again, I – kind of in the brainstorming mode here and so I’m sorry if we get too granular but, taking the ASIAs model and thinking abo – and I really, I can’t emphasize enough the difficulty about keeping this starting small and building, so it succeeds and gains momentum and then others want to come in. But the difficulty of maintaining that because as we go through this process, these things tend to get expansive and bigger. But I would look – governance theory suggests that boards of 8-12 tend to work better, because they’re small enough for everybody to participate but big enough to get input.

So probably look at a 10-12 person advisory group, and I would probably design it that the membership is defined by institutional membership; because you want to get big enough entities that the entity can carry the water over time, not individuals. And so that's why I said it would probably go to a group like EHRA and ask, can you query your own group about who are some of the best vendors maybe to participate and look at some health system people, like I said, the provider groups. I have my conflict to disclose, I think the ANA and the AMA are probably the two biggest entities for nurses and doctors and they are for the country, but they would have the staying power to support something like this. And I would, in the initial design, say that this is the way it's going to begin and not overdesign the structure and scope some basic things for them to get going in a 6-18 month kind of timeframe. And then build in in the initial design that the goal would be to become more inclusive, larger and to redesign that structure as we go forward.

So I wouldn't try to over-orchestrate from the get go, that we want to have a 40 member group and this and that, because I think that that's going to tie us in in ways that will not allow it to grow in the way the ASIAs model did. And I think if the earlier group is successful and demonstrating value and creating a core set of things they do that are useful I think that the value proposition will sell itself. And this will be able to grow in the way that it is most useful as opposed to some incorrect way we try to prescribe if from the front-end.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Yeah, I mean –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

This is Paul Tang –

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

– we clearly don't want to micromanage at this point.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

This is Paul Tang let me maybe complement what Steve said. I agree with his 8-12 – I mean I agree with his smaller number, especially the starting – when you start small because you really want to work on content versus controversy. I might offer a complimentary perspective on what Steve is proposing in terms of using organizational members. I understand the need to have the backing, but I'll give an exa – if you look at the ASIAs group members that he put on the screen, it was predominantly individual companies, and they did have some role in the bottom right for organizations.

As an example, I'll use you as an example Steve. I would rather draw on your expertise, experience and perspective as an individual than on your role within a large organization. Because I'm a little nervous that you may – if you come in representing an organization, then you need to represent that organization or one might feel you need to, and that can be encumbered by other positions, etcetera. So I just offer that as a complement in terms of saying maybe we ought to also consider the possibility of picking individuals rather than groups. HIT Pol –

Steven J. Stack, MD – Chairman – American Medical Association

If I may –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

– Go ahead.

Steven J. Stack, MD – Chairman – American Medical Association

Paul, this is Steve. I don't disagree with that, actually I think that that's a useful addition to what I was saying in that you may ask, and we do this all the time, right. So large groups populate or have slots that they put, but then when people become a member of a new board, their obligation is to that new board and not to their sponsoring society. So I think it's pretty easy that you define that on the front end, that someone may suggest a person, but that it's understood when they become – they inhabit that role, I think then their obligation is to that new role and not just to advocate the policies of their sponsoring organization. But – and that's why I think that we should define this on the front end, that it's all subject to revision 18-24 months after it starts so that – because I don't think we want to be locked in to that initial structure, but that initial structure is probably a more effective way to get it going.

Margaret “Peggy” Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety

This is Peggy Binzer, I don't – I agree that starting – using a workable approach is the best way to start. But I did want to urge caution that once the priorities are established, we may not want to limit data sources from the beginning if a priority has been established and there are multiple organizations that have data that can contribute to developing a best practice or contribute to the learnings, they should be able to participate as well. And I'm just thinking of all the patient safety organizations who have been collecting data for a long time.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

That makes sense. Other thoughts?

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

And so –

Mary Beth Navarro-Sirio, RN, MBA – Vice President, Patient Safety Officer – McKesson Corporation

Yes David, this is Mary Beth. I would agree that – with the concept that we have already talked about, kind of trying to keep this small and not boil the ocean. And that probably one of the very first priorities for the center should be to help us aggregate the different data sources and figure out where we really need to focus and kind of get started in a small way. I guess the one question I had related to something that was on one of the slides was just this whole idea of whether the center will or won't function as a PSO, because I think that could be a very important distinction and it could impact how everything kind of flows. And I think there are a lot of issues with how at least the vendor community currently can interact with PSOs and the protections that are provided. So I think that we probably should have a conversation about that, too.

Margaret “Peggy” Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety

And this is Peggy Binzer, I agree with that. The vendors currently don't have confidentiality protections and that is actually critical to have a culture of safety so that everyone really is safe with the information. We also with the safety center, although the safety center wouldn't have protections of a patient safety organization without some sort of authorizing statute giving them the authority to give confidentiality protections, there are ways for the safety center to work within a PSO in a limited capacity. So even though they don't have the protections, there are ways to have the safety center work within the PSOs protections.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Yeah so Peggy, this is Toby. Is what you're getting at is that so would the center sort of be an analytical contractor to – could be an analytical contractor to a PSO? And again, not to get into, and I'm not a lawyer, so not to get into any of the legal issues, but I think what's important here is that we have to ensure that that data is protected.

Margaret "Peggy" Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety

Yeah, absolutely Toby, you're absolutely right. And those protections are very limited, whoever represents the center as the analytical expert, for example, because the center is developing best practices, for example, they wouldn't be able to share any of the confidential information with any of the board members or any other people. So it really is limiting in that regard.

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

This is Tejal. I mean I wonder if – so for the analytic piece and the compiling of all these data streams and all that, it seems like having the protections for the analytics would make sense, to reassure the folks sending in the data and so on. But then there's sort of that second layer of then taking what's learned from the analytics, which hopefully is completely de-identified at that point, and then determining okay, how do we determine best practices or convene around this issue or so on. And that piece to me should not be in this protected space, but should be just as transparent as possible in terms of trying to identify those best practices. So I don't know whether there's a way to have a component of it, like the analytics, be under the PSO protections but not the rest of it.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Good question. I mean it's been hard for me to imagine how any one PSO would have access to all the various data streams that would be needed.

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

Yeah, I mean, most PSOs from my understanding, are getting safety reporting data, but you think about even that, if you look at things like walk arounds or complaint data or other things and a lot of other issues, not to mention the vendor data and things that the vendor community has and so on. So we're talking about a lot of different data streams.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Yeah and I think we need to make sure that those data streams are protected from legal recourse, yet available for building best practices and improving quality and safety.

Steven J. Stack, MD – Chairman – American Medical Association

So this is Steve again. On the PSO topic, I still, and again I'm all – I'm just very open to anyone else who has a broader perspective, because I don't have this broad perspective. I don't have enough knowledge of the diversity of the PSOs. But my a priori supposition is that most entities have created these PSOs to achieve very specific purposes for their entity and the principal reason for creating it is to avoid the release of information that would subject them to liability. That's an overly simplistic way, but I think the vast majority of them are not specifically focusing on health IT at all, in fact, are probably focusing on things specifically of concern to their own health enterprise.

So I would not want to design this safety center in such a way that it really relies on any direct or profound way on just PSOs. I would think we'd be better off to have that initial group of people focus in the beginning on how can you voluntarily share data in a way that's de-identified, that does not create in its own way, hopefully, legal peril for the people contributing to it. And then how or what existing laws, statutes, regs can they use in the design of their work to help provide protections or security. And then some PSOs may be invaluable to contributing things, but I think the multitude of them will probably have little to nothing to offer to this specific activity.

Margaret "Peggy" Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety

Yes –

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Hey Steve, its Jon White. I will defer to Amy Helwig, if she is on the phone, to give you a slightly longer exposition on PSOs. Amy, are you there?

Amy Helwig, MD, MS – Medical Officer, Office of the Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Yes.

P. Jonathan White, MD – Director, Health IT – Agency for Healthcare Research & Quality (AHRQ)

Are you willing to address some of the things that Steve just brought up?

Amy Helwig, MD, MS – Medical Officer, Office of the Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Can you just – Steve, can you just – your highlights again?

Steven J. Stack, MD – Chairman – American Medical Association

Well it was just that I think most entities that have PSOs created them for very specific purposes for their own health enterprise. So, if it's a physician group or if it's a health system, they probably have unique challenges and they focus on those challenges. And I don't think health IT, for many of them, is going to be a principle focus of their activity. So I would suspect that a lot of them don't have a lot to offer specifically on health IT. And then secondarily, I think they create it mostly for their internal use and even though there's external reporting possibilities anticipated apparently in the statute or the regs, I don't suspect that most of them are really dwelling in great depth about sharing things externally, they're using it internally for their organization as their primary focus.

So I don't want us to over-rely on PSOs, I don't want to exclude them and for those that can be very helpful, I think we want to support that. But I would suggest that we need to have a different kind of voluntary model that's created that allows PSOs to participate, but that gets information a lot of other sources or we're going to find ourselves with a very thin pipeline of data coming in.

Amy Helwig, MD, MS – Medical Officer, Office of the Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Sure, a couple of comments. Regarding PSOs in general, they are very broad and a lot of variety in terms of the quality and safety that they can cover, because the Patient Safety Rule itself was very broadly written. So I believe there's – the number of PSOs right now are somewhere in the 70s. There are some that are very small that are very focused on one small niche area, for example, there's one that's dedicated to pediatric anesthesia. But there are PSOs that are very broad and working with many different types of healthcare providers on the whole spectrum of quality and safety and then there's every variation in between. So you certainly do see like some specialty groups or some smaller professional organizations or some that are maybe focused on one area or region of the country, but they can operate quite widely. They can receive a whole set of data and there's no limit to the number of PSOs that can function. They are not funded by the government in terms of their operations, but if – new PSOs can form at any time and PSOs can change their focus at any time, too. So it's really a flexible rule in that regard.

In terms of the PSOs that are contributing to a national aggregate center and what's called for in the law and what is operating as a network of patient safety databases. And again, that's what Bill Munier talked about last week; it really just depends on what type of information or what their focus is. So some are gearing up to submit data, it depends on what type of data their receiving, because it does need to be in the Common Formats in order for it to be aggregated on a larger level. But there certainly is potential and really no limits with the number of PSOs and also where they can operate within the United States.

Margaret “Peggy” Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety

And this is –

Steven J. Stack, MD – Chairman – American Medical Association

So you now, I – go ahead, Peggy.

Margaret “Peggy” Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety

I just wanted to follow up on that with greater specificity. There are many PSOs that are already working with either providers on some HIT issues or clinical issues that also intersect with HIT. And then there are many, many vendors who have stepped forward and are working with PSOs to really determine the value and looking for greater information. I can mention that ECRI, of course, has and has talked about their pilot that they have multiple vendors as well as athena and the Quantros partnership where athena actually paid for every one of its clients to be a member of a PSO to make reports of all clinical errors, near misses including any HIT, if there are any. Pascal Metrics has multiple partnerships as well. So we're already seeing the growing and development of true information collection system.

The reason that the protections are necessary is that there's an IOM to err – the report to err is human in 1990 said that what we really need to do is allow healthcare providers to talk to each other about errors, unsafe conditions, near misses so that we can learn from them. And the problem is, without protections, there's such fear of liability, regulatory action, and other things that it really doesn't foster the conversation. And so looking at the VA model where the VA provides very strong confidentiality protections under the Social Security Act, the Patient Safety and Quality Improvement Act was established and established very broadly to be an experiment to be able to collect information and to talk about the information. So yes, there are protections, but under the law, there has to be a quality improvement component in order for the protections to actually lie. So in that, that's why AHRQ runs the program and other things. But what we've found is that the confidentiality protections are the most important piece to allowing physicians and others to really share sensitive information about what's happening in the clinical environment.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

So I think based on the – this is Toby, based on the discussion we had earlier, it seemed like everybody was in agreement the PSO would be one of the data sources, but clearly not the only data source. And I think that that's very important, so we have multiple data sources. As far as confidentiality is concerned, any data, and the lawyers on the phone can correct me if I'm wrong, anything that comes through the PSO is work – is patient safety work product and therefore comes under the PSO protection. However, what my question is, what about the data that we get from non-PSO sources? We have to ensure that that data is protected as well. And so that's where some sort of relationship with another PSO might be a way to accomplish that protection for that other, probably much larger, group of data that we'll bring in. Did I lose everybody?

Margaret “Peggy” Binzer, JD – Executive Director – Alliance for Quality Improvement and Patient Safety

No and I agree with that Toby. When you look at organizations that don't have protections, what you tend to see is information that would be made public or has been made public and you don't get the very rich, near miss information that is so critical. And that's why the safety culture is really necessary if that's the type of data that we want to collect. But we also agree as PSOs that we're not the total solution, that we're only a data source – one data source.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Well, that's helpful. Other thoughts or comments?

Jodi Daniel, JD, MPH – Director < Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

This is Jodi Daniel – one question about something that hasn't been discussed, which is just the role of the patient or consumer in the safety center and if folks have any thoughts about that. We're focusing on patient safety and whether like the governance structure should include patients or how we make sure that we are kind of thinking about things from a patient's perspective. Any thoughts?

Tejal K. Gandhi, MD, MPH, CPPS – President – National Patient Safety Foundation

This is Tejal. I mean, I think the governance structure definitely needs to include that patient voice, once that gets cleared up in terms of exactly how that's going to work. But I think absolutely having patients in that structure is going to be critical.

Steven J. Stack, MD – Chairman – American Medical Association

This is Steve Stack and I agree with that. I think that we definit – I mean we're all doing this for the benefit of patients, so I agree with that. My qualifier though would be, I think we need to be careful and again, I don't – not to mention specific examples, but just to make the point. Whether it's a big group like AARP or Consumers Union, I think we need a group that has eno – that's big enough and is subject in some way to the pressure of a multitude of consumers so that when they come and they advocate or give perspective that they're coming from a bigger base.

I think where we need to be careful is too often the "patient voice" is an anecdotal individual's perspective without the benefit of some broader accountability. And I know this is just like a third rail to even make these kind of comments, but I mean I'm a patient, I have to go to a doctor and hospital and get care, so does my family, so we're all patients at one time or another. So I think what we're looking for is people who come from the perspective of what is generalizable to patients in a generalizable way, not anecdotal one-off perspectives, which have us go down rabbit holes at times, which are not necessarily helpful to the broader population.

W

I agree with that. I think representing a broad swath of patients as opposed to kind of "only an individual" or a very niche group would make sense, given the breadth of what we're talking about.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

And that's worked well in the Policy Committee, for example, but I agree, I think that makes sense. What about patient reports as being one source of data?

Steven J. Stack, MD – Chairman – American Medical Association

Absolutely, I mean if they are subject – this is Steve again, if they're subject to an experience that was not ideal, I think we want to take – you want to have a bro – what's the term they use in health IT, you want to be very liberal in what you accept but very focused in what you transmit. So, I think we want to – we would not want to close off that as a source for reporting.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Okay. Good. So, I'll add both those points, thank you Jodi for bringing that up.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Thank you all.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women's Hospital & Partners

Other thoughts or comments? Okay, well good. This has been a really rich discussion today. What I'll be doing between now and the next time is taking what we've learned today, updating the slides and refining them, making some changes. And then we'll go through a new set in our final meeting, which will be July 7. I would just encourage everybody who – to take a look through these, if you have any thoughts about how they should be changed or edited, just go ahead and send me an email and I'll – we'll work on getting those changes incorporated. I think today's discussion has been a really, really good one, it was especially helpful to hear from ASIAs and that does have a lot of parallels with what we're thinking about, even though it's not exactly the same sort of thing. Any last comments? Okay, Michelle, could you go ahead and open it up for public comment?

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Sure. Operator, can you please open the lines?

Rebecca Armendariz – Project Coordinator - Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you are listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

David Bates, MD, MSc, FACMI – Senior Vice President for Quality and Safety, Chief Quality Officer – Brigham & Women’s Hospital & Partners

Great. Well thank you all, happy Fourth of July everybody and we’ll be talking to you shortly after that.

Tobias C. Samo, MD, FACP – Chief Medical Officer – Allscripts

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thank you.

Steven J. Stack, MD – Chairman – American Medical Association

Thank you.

Michelle Consolazio, MPA – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you.

Public Comment Received

1. Just food for thought: is there a way that Regional Extension Centers could assist?